510(k) Summary of Safety and Effectiveness

K062953

This 510(k) summary of safety and effectiveness information is submitted as part of the PreMarket Notification in accordance with the requirements of 21 CFR Part 807, Subpart E and Section 807.92.

1. Identification of Submitter:

Submitter:	Medisystems Corporation
Address:	701 Pike Street 16th Floor Seattle, WA 98101-3016
Phone:	206-834-1238
Fax:	206-834-1201
Contact Person:	Ms. Laura Plath Manager, Product Surveillance
Date Prepared:	January 26, 2007

2. Identification of Product:

Trade name:	Medisystems Hemodialysis Fistula Needle Securement Device: ***SiteGuard***
Regulatory Number:	21 CFR §880.5210
Regulation Name:	Device, Intravascular Catheter Securement
Common name:	Fistula Needle Securement Device
Regulatory Class:	Class II
Product Code:	KMK
Classification panel:	General Hospital
Manufacturer:	Medisystems Corporation 701 Pike Street 16th Floor Seattle, WA 98101-3016

3. Indications for Use

The Medisystems Hemodialysis Fistula Needle Securement Device, SiteGuard, is intended for use to secure the fistula needle to the patient's skin.

The SiteGuard needle securement device has the following features:

a. It allows the needle to be held at a consistent angle during treatment;
b. It secures wing/hub to the patient's skin and helps prevent movement and/or dislodgement of the needle during use; and,
c. It helps to immobilize the patient's vein or access during cannulation so that it is not necessary for caregivers to hold the vein or access with their fingers.

4. Device Description

The subject of this 510(k) is a removable, rigid plastic securement device that is attached to the AVF needle set by the care giver. The SiteGuard securement device will be included in the unit packaging pouch with the Medisystems AVF needle set and also will be available for purchase as an individually packaged accessory.

Because the tape, the AVF wing, and the patient's skin are flexible, the needle may dislodge or move within the patient's access during treatment due to this inherent flexibility. The securement device adds a rigid structure to increase the ability of the tape to prevent the needle from accidentally dislodging or moving within the patient's vascular access.

This accessory also will immobilize the patient's vein during insertion of the cannula so that it is not necessary for caregivers to hold the vein or access with their fingers. The channel along the bottom of the securement device is designed to immobilize the patient's vein during insertion. This feature is especially helpful for patients who have newly created fistulas or implanted grafts because new accesses tend to move during cannulation.

5. Comparison with Legally Marketed Devices

The marketed devices which are substantially equivalent to the SiteGuard securement device are as follows:

- TNT Moborg Intl., LTD, Immobile Non-sterile and Immobile A/C non-sterile (K941850); and,
- TNT Immobile sterile and Immobile A/C sterile (K941940). This 510(k) has been supplemented with the Immobile FST product, which is designed to provide fistula access needle control.

**The term "substantially equivalent" as used in this premarket notification is intended to be a determination of substantial equivalence from an FDA/regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable and does not diminish any patent claims related to this product or to the technology used to manufacture the product.*

6. Safety and effectiveness

To assure that the devices are safe and effective, all finished products are tested and must meet all required release specifications before distribution.

The required testing is defined by written and approved procedures that conform to the product design specifications.

7. Conclusions

The SiteGuard Fistula Needle Securement Device, is substantially equivalent to the identified legally marketed devices. Both manufacturers' products are provided sterile and non-sterile. Both manufacturers' products are used during cannulation for fistula needle access control and for subsequent securement of the vascular access device. The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and verification and validation testing processes. There are no new issues of safety or effectiveness resulting from the inclusion of this accessory in the legally marketed needle set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Laura Plath
Manager, Product Surveillance
Medisystems Corporation
701 Pike Street, 16th Floor
SEATTLE WA 98101-3016

FEB 1 2 2007

Re: K062953
Trade/Device Name: Medisystems Hemodialysis Fistula Needle
Securement Device: ***SiteGuard***
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: January 30, 2007
Received: January 31, 2007

Dear Ms. Plath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections.531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K062953

Statement of Indications for Use

510(k) Number: K062953

Device Name: Medisystems Hemodialysis Fistula Needle Securement Device: ***SiteGuard***

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062953